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(54) **INTRAVASCULAR DEVICE WITH CARRIER TUBE ENGAGEMENT MEMBER**

(75) Inventors: **Timothy McGlinch**, St. Paul, MN (US); **Tim Mlsna**, St. Michael, MN (US); **Dean A. Peterson**, Brooklyn Park, MN (US); **David B. Robinson**, Chanhassen, MN (US)

(73) Assignee: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

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A61M 25/16 (2006.01)

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See application file for complete search history.

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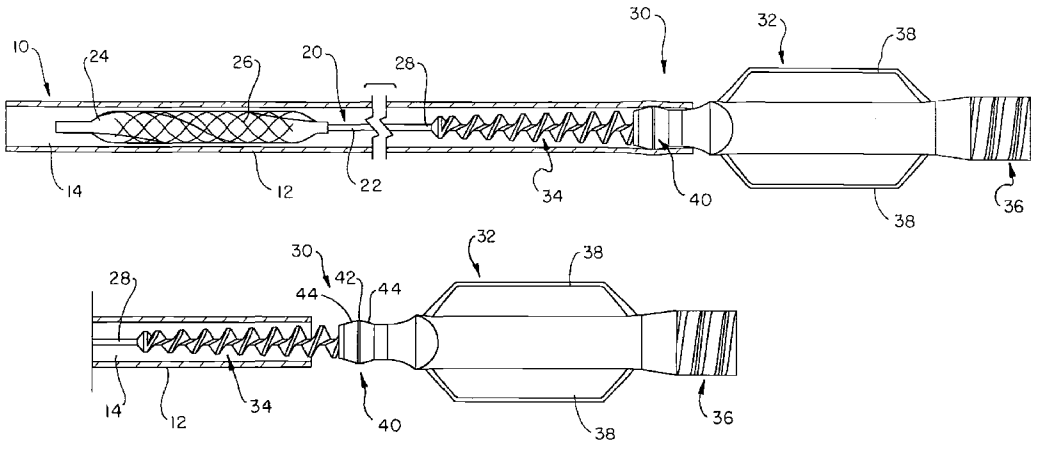
Primary Examiner—Nicholas D. Lucchesi
Assistant Examiner—Christopher D. Koharski
(74) *Attorney, Agent, or Firm*—Crompton, Seager & Tufte LLC

(57) **ABSTRACT**

An intravascular device having an elongate shaft and a proximal hub assembly. The proximal hub assembly includes an interference fit member (IFM) which forms an interference fit with a carrier tube to reduce the tendency of the device to fall out of the carrier tube during handling and to provide for easy removal of the device when ready for use.

7 Claims, 12 Drawing Sheets



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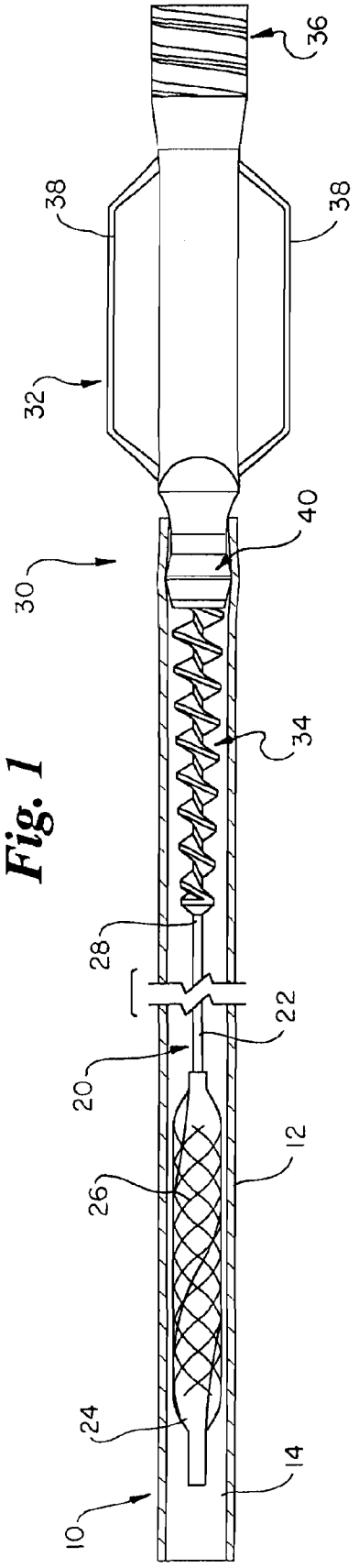
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Fig. 1

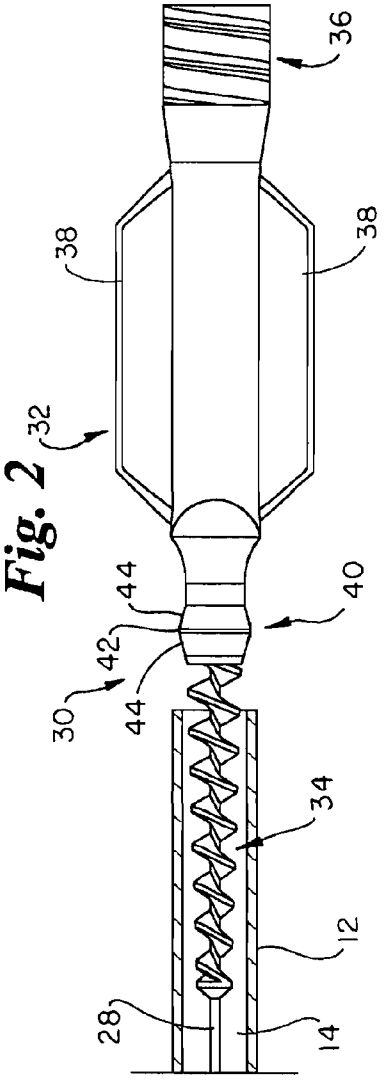
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Fig. 2

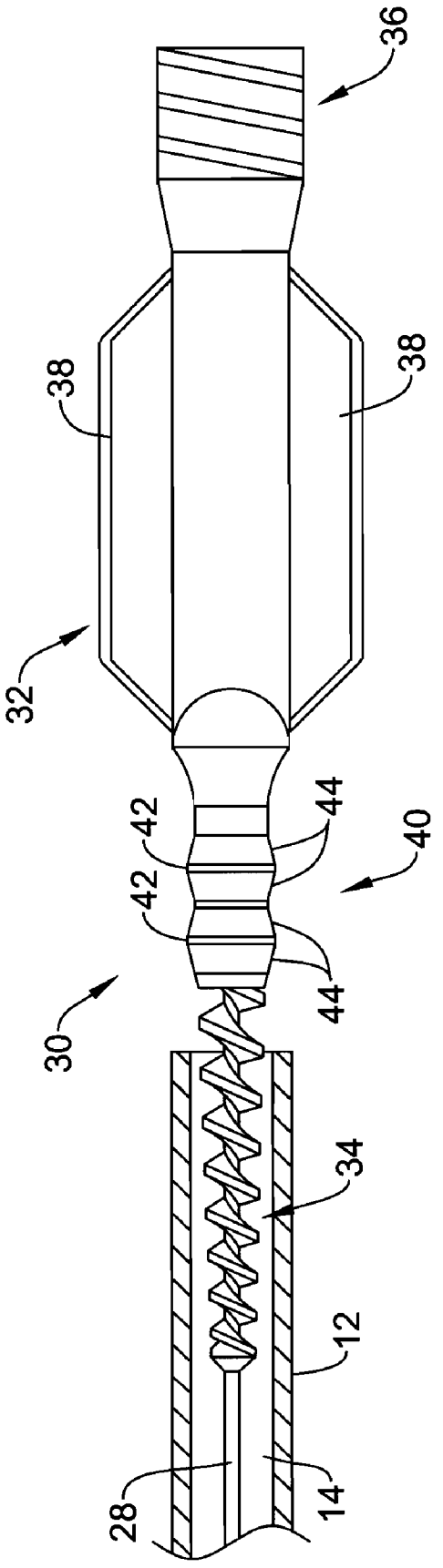

Fig. 2A

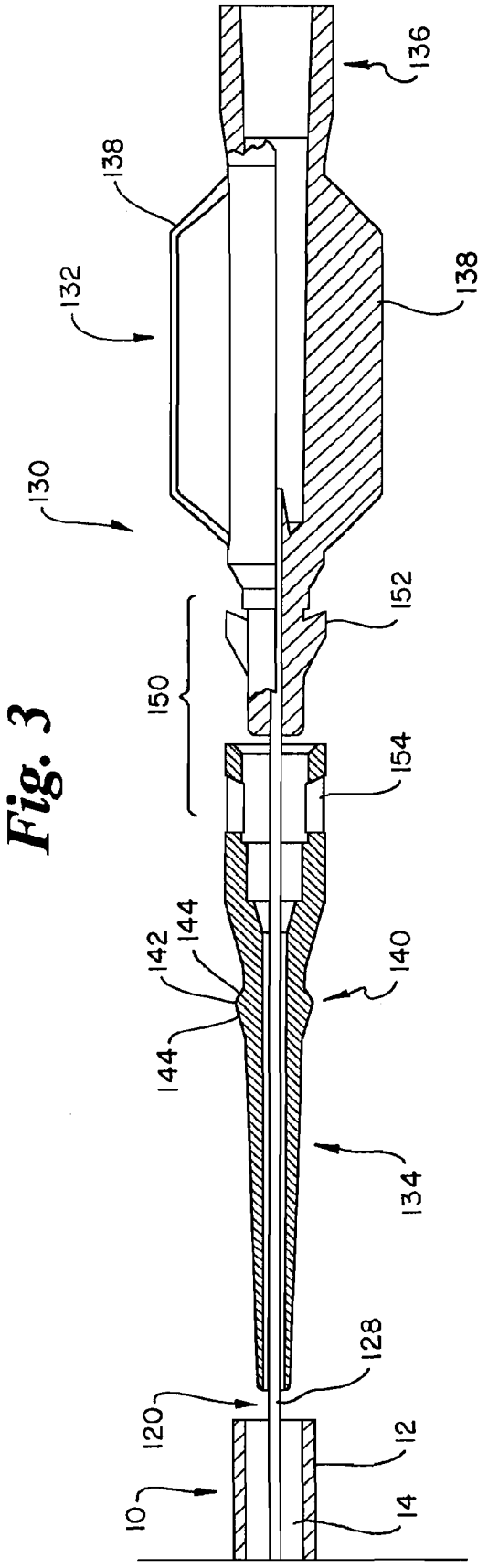
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Fig. 3

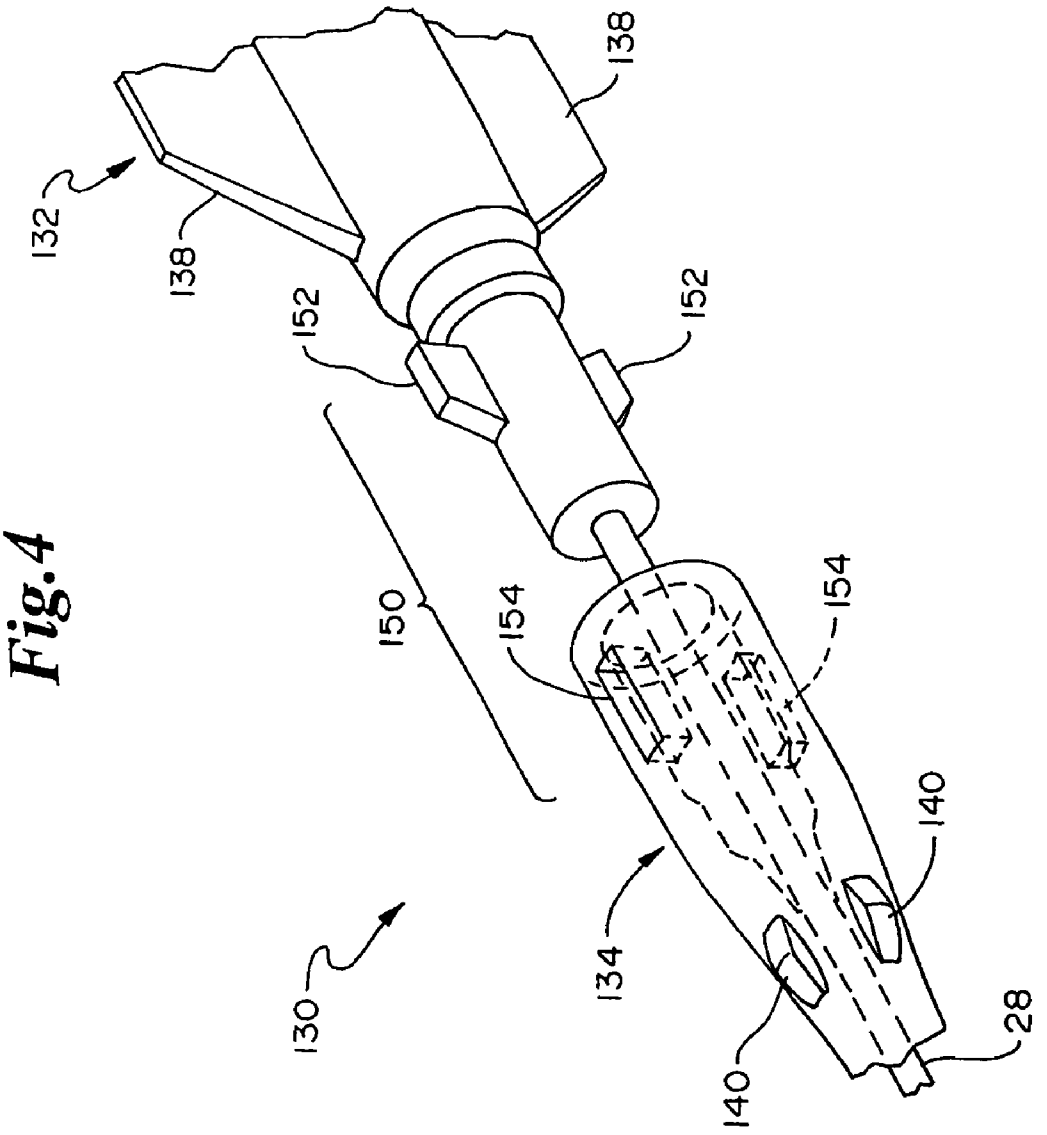

Fig.4

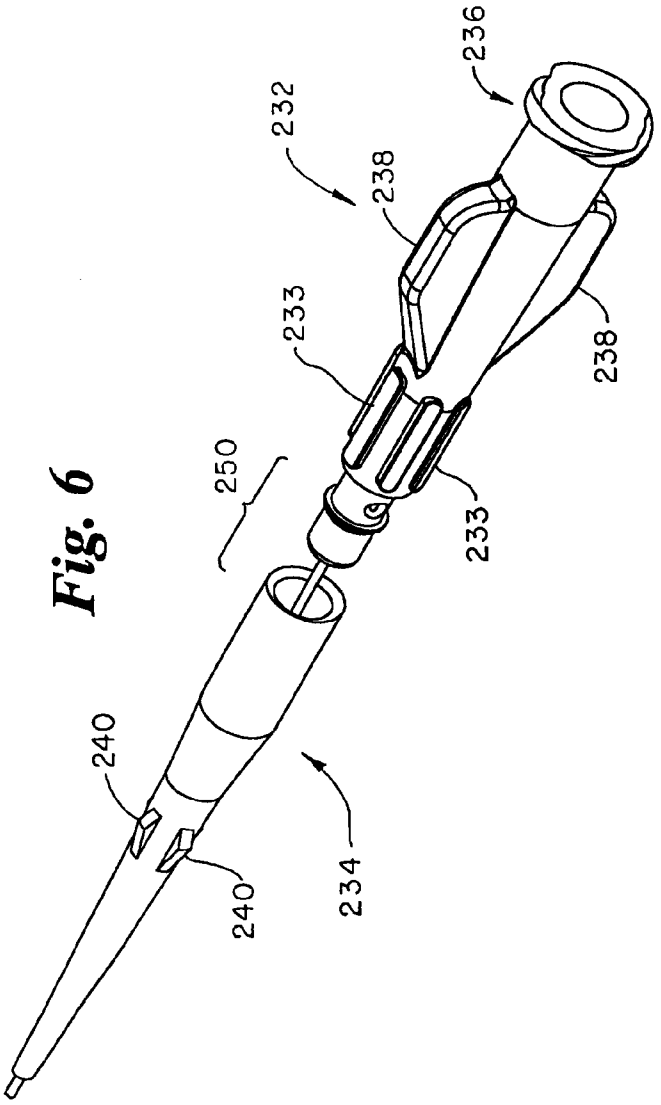
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Fig. 6

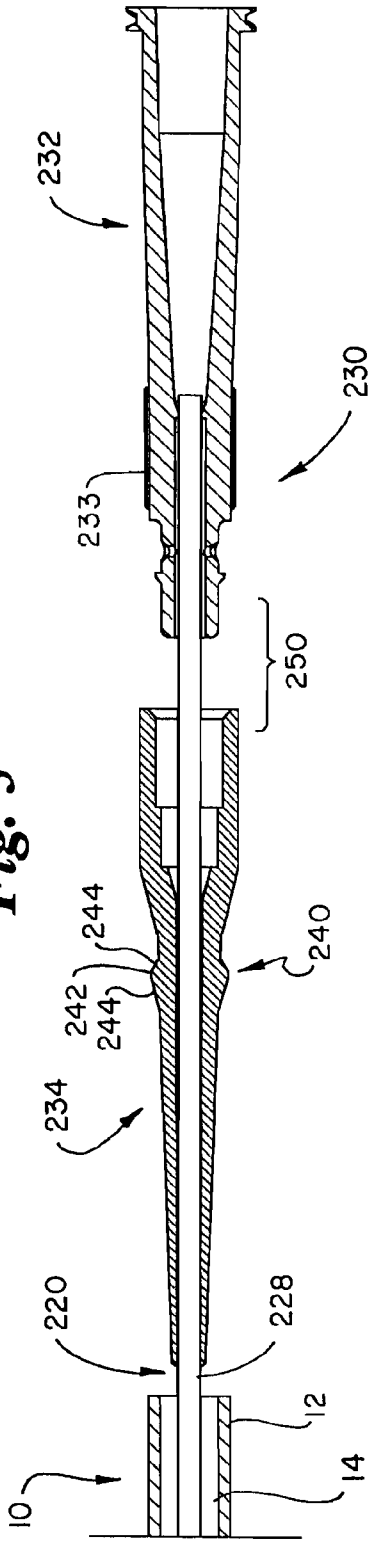
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Fig. 5

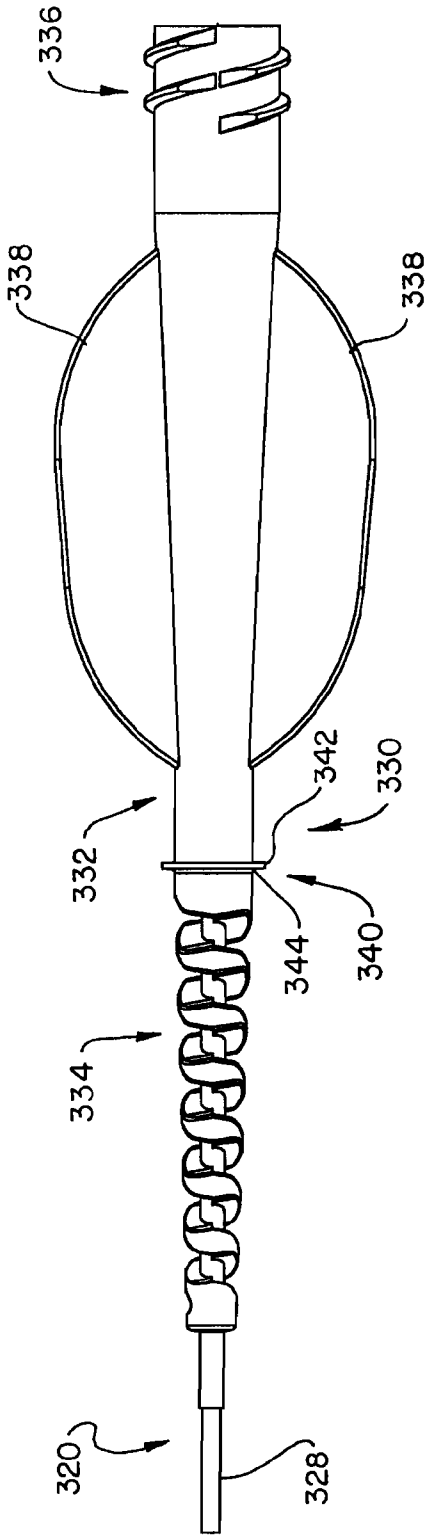
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Fig. 7

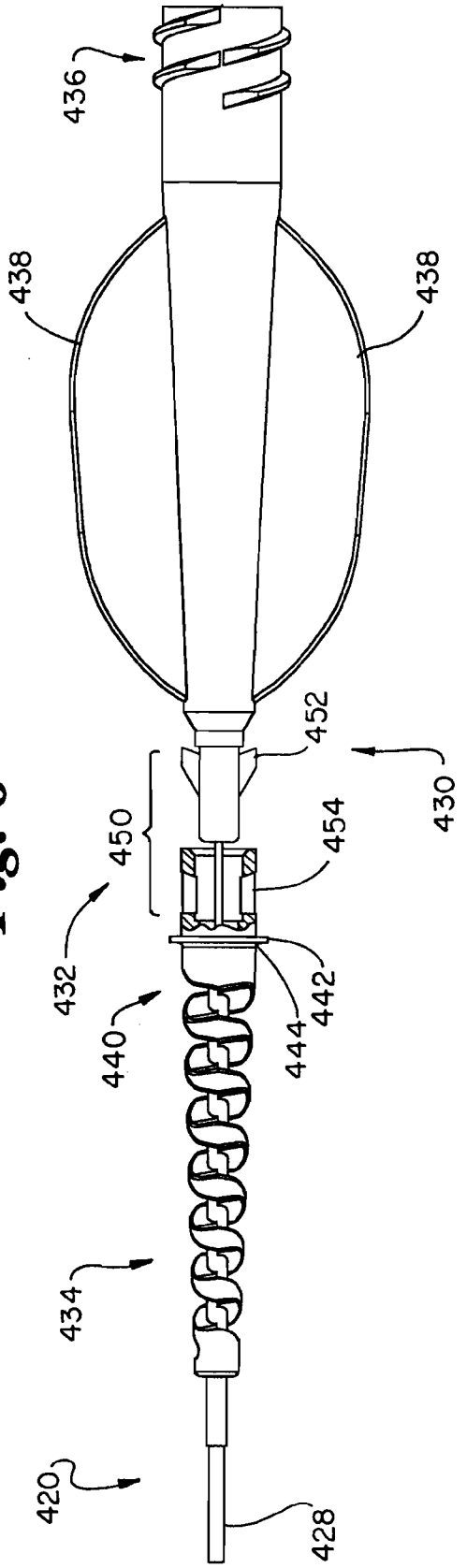
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Fig. 8

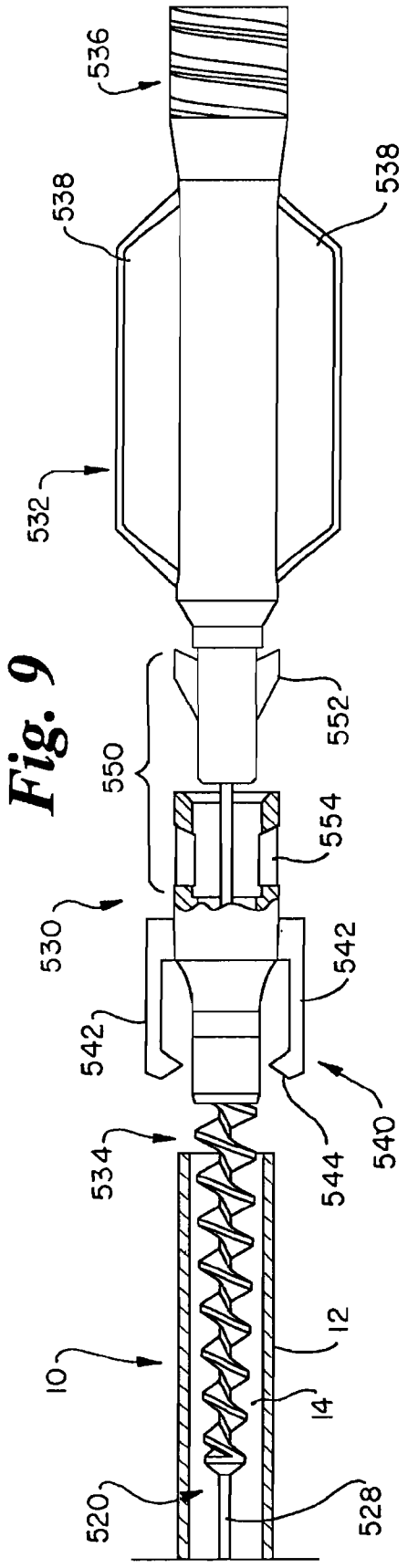
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Fig. 9

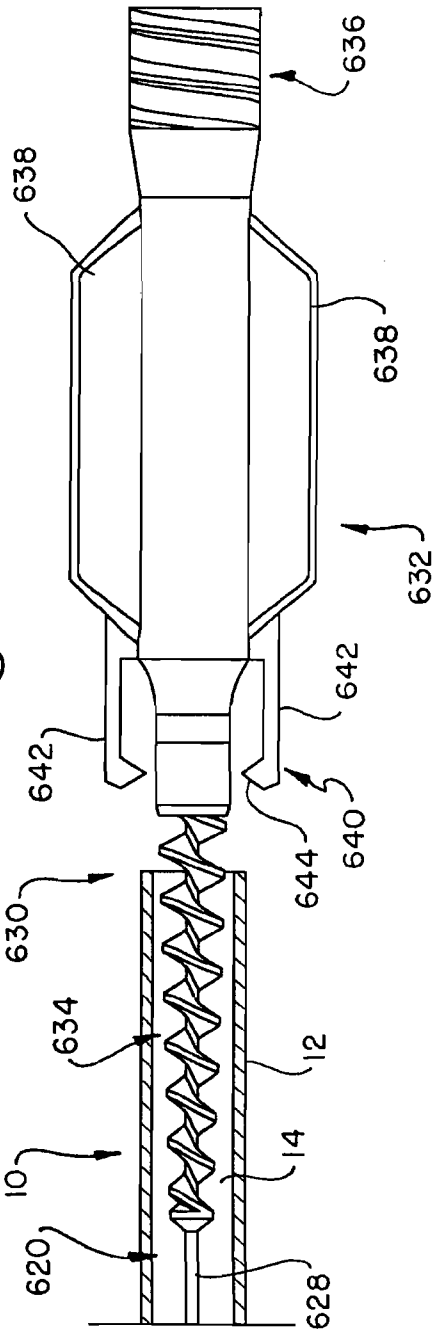
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Fig. 10

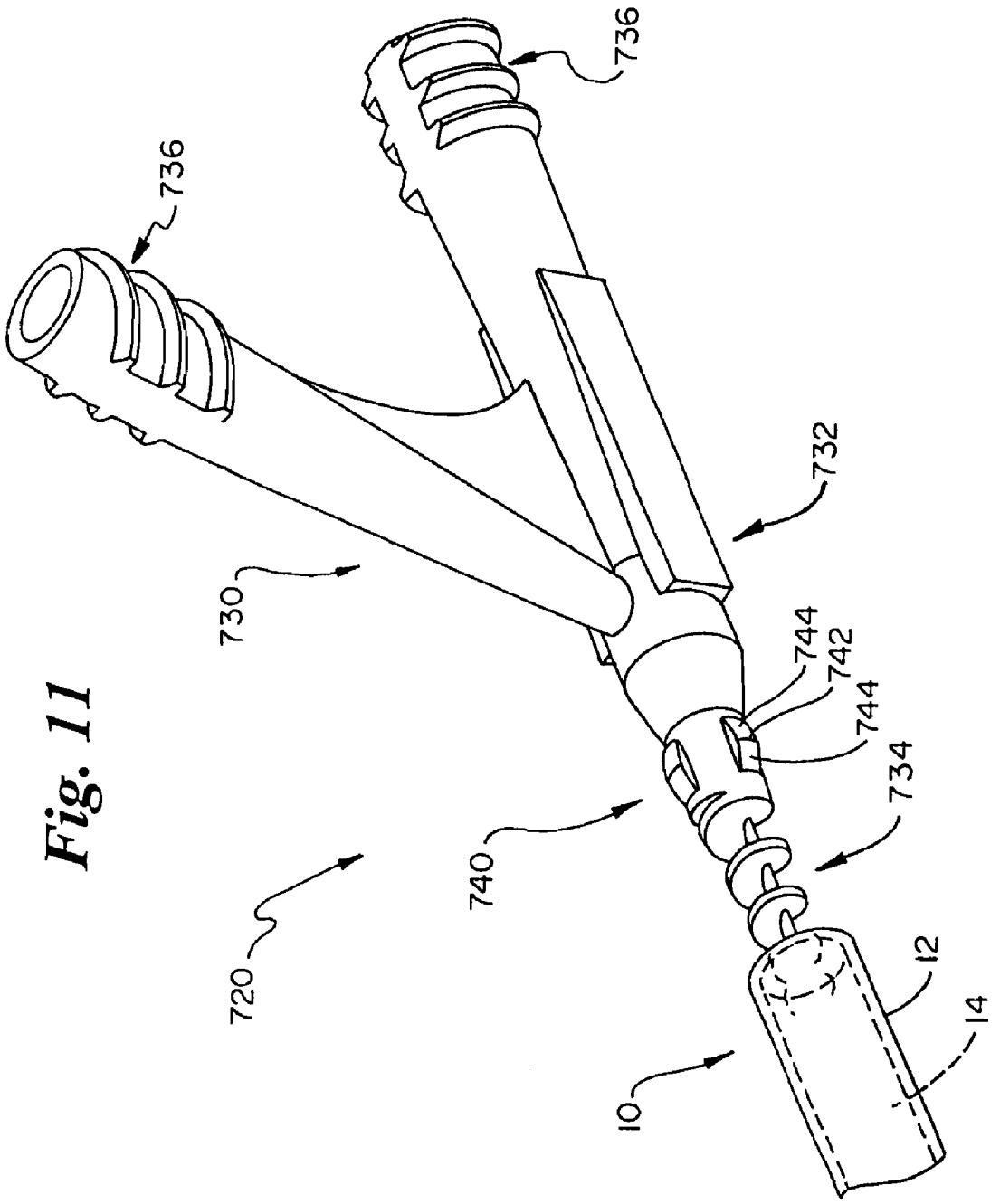

Fig. 11

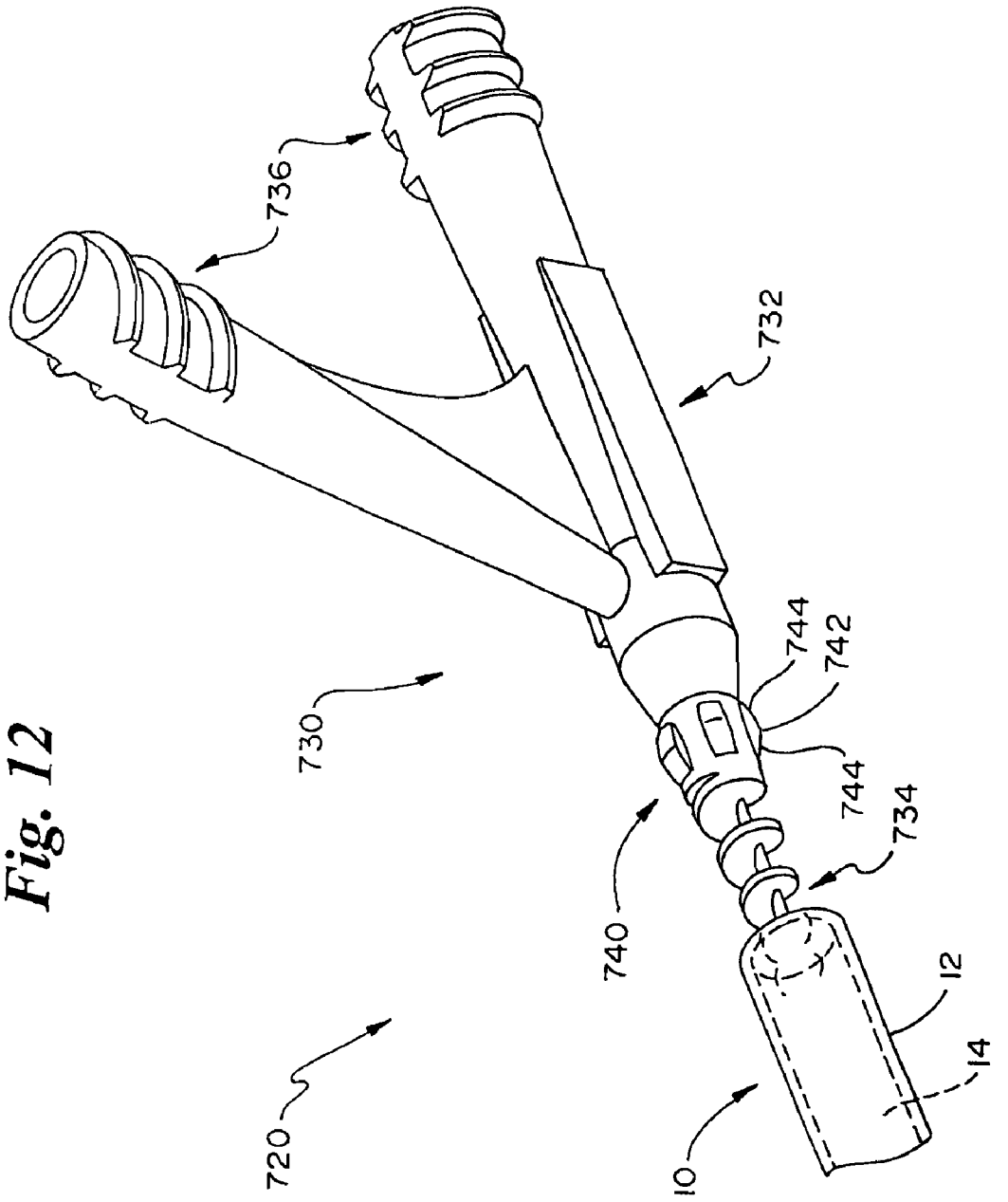

Fig. 12

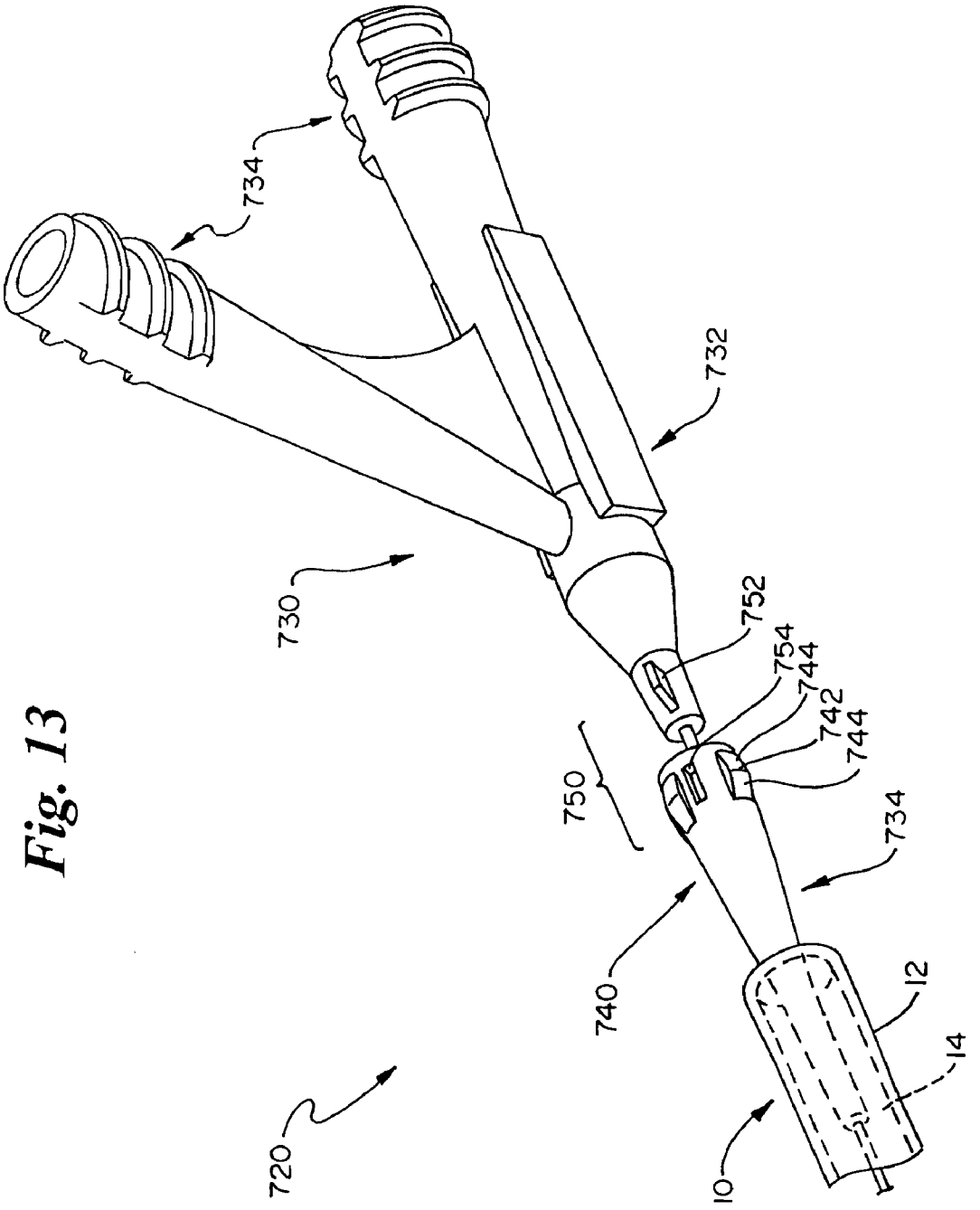

Fig. 13

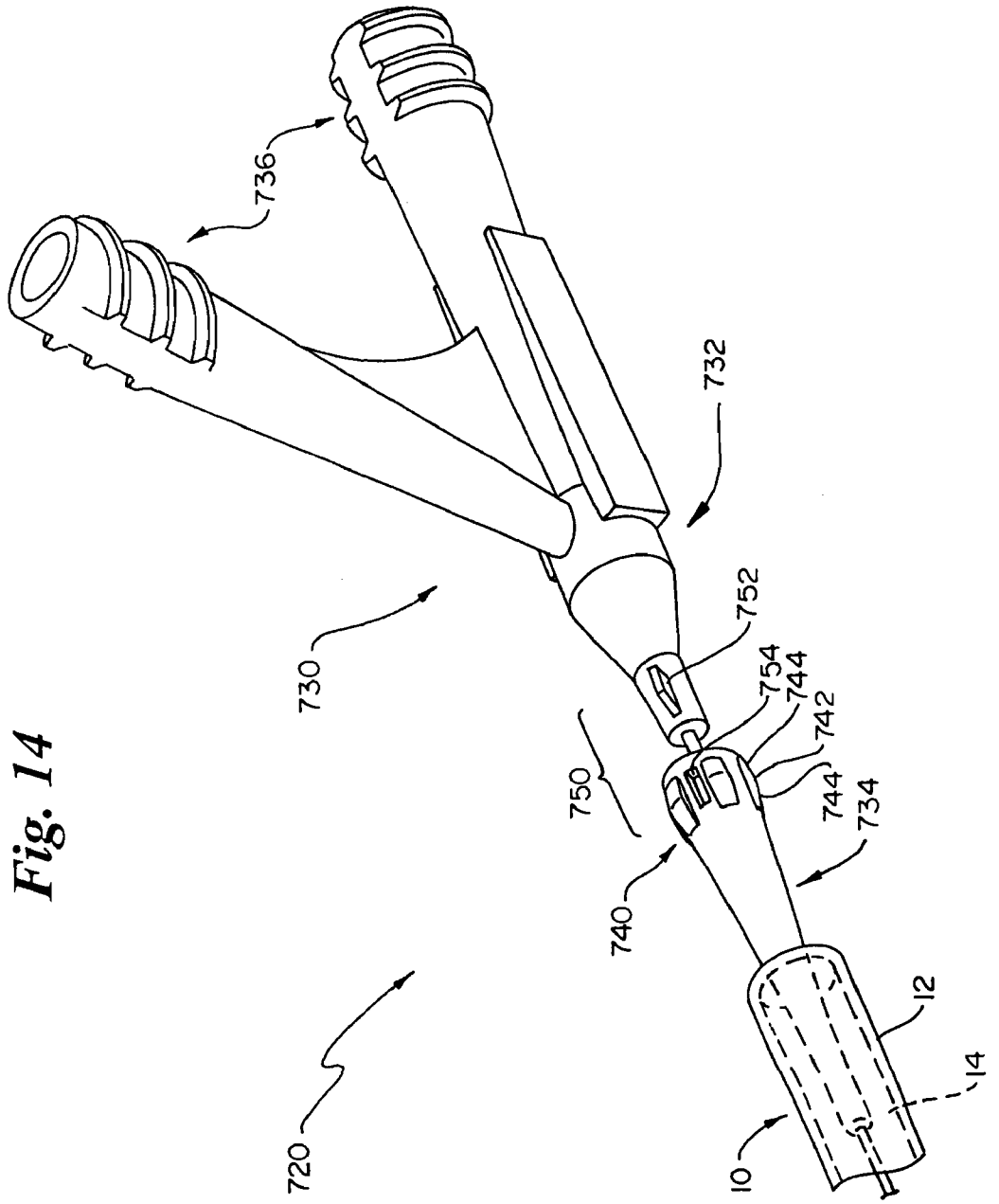

Fig. 14

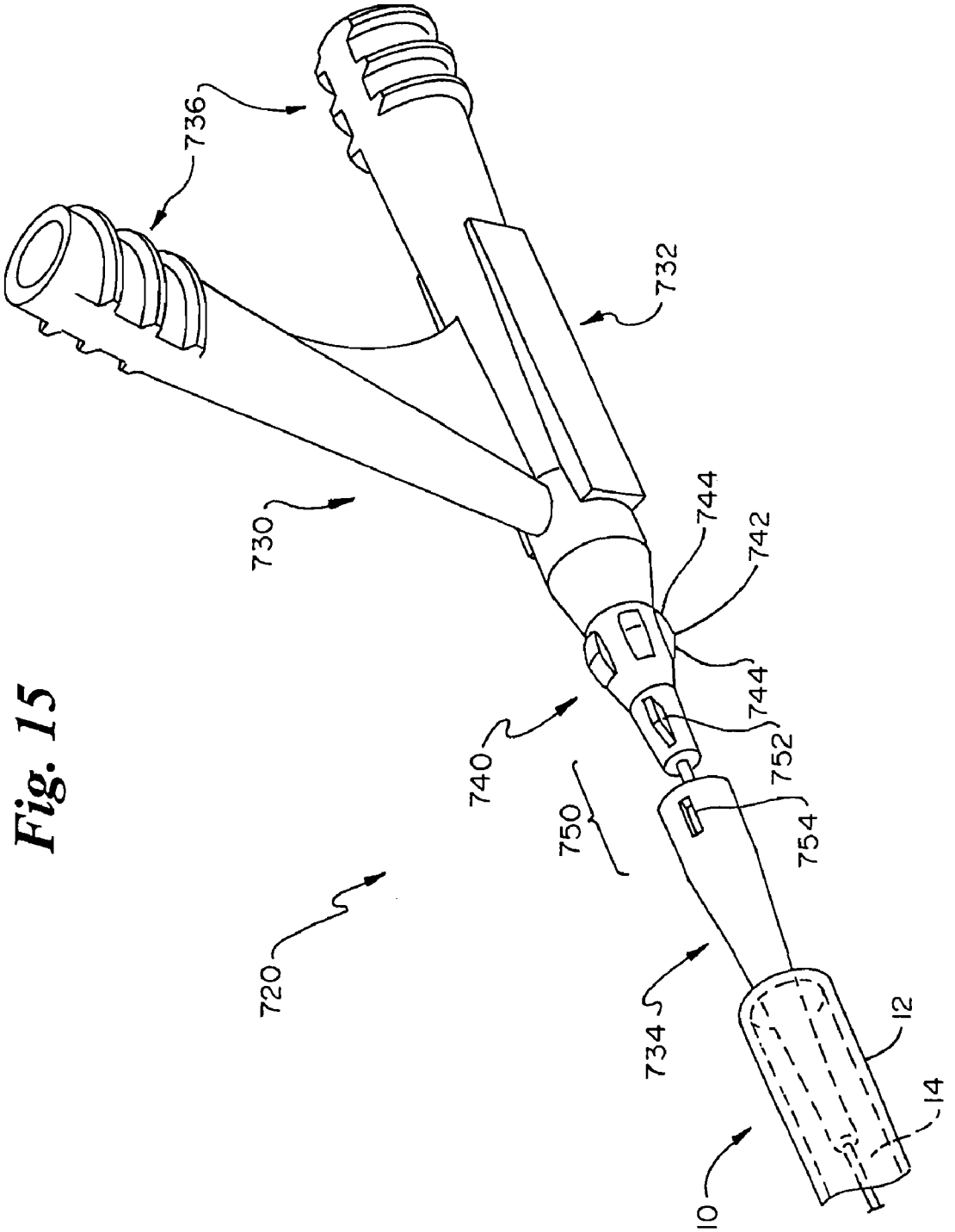

Fig. 15

INTRAVASCULAR DEVICE WITH CARRIER TUBE ENGAGEMENT MEMBER

FIELD OF THE INVENTION

The present invention generally relates to medical devices and packaging methods therefor.

BACKGROUND OF THE INVENTION

Elongate intravascular devices such as balloon catheters and guide wires are often packaged in carrier tubes. A carrier tube provides a convenient way to package and handle an otherwise unwieldy intravascular device, but the intravascular device may have a tendency to fall out of the carrier tube. As such, there is an ongoing need to provide improved devices and packaging techniques to reduce this tendency.

SUMMARY OF THE INVENTION

To address this need, the present invention provides a number of alternative solutions. In one embodiment, for example, the present invention provides an intravascular device having an elongate shaft and a proximal hub assembly. The proximal hub assembly includes an interference fit member (IFM) which forms an interference fit with a carrier tube. The interference fit reduces the tendency of the device to fall out of the carrier tube during shipping and handling, but provides for easy removal of the device when it is ready for use.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a partially cross-sectioned plan view of a catheter disposed in a carrier tube, wherein the catheter includes a single port hub assembly having a hub and an integral strain relief, with an IFM disposed on the hub, showing the IFM engaged with the inside surface of the carrier tube;

FIG. **2** is a partially cross-sectioned view of a proximal portion of the carrier tube and the catheter illustrated in FIG. **1**, showing the IFM disengaged from the carrier tube;

FIG. **2**A is an embodiment similar to that shown in FIGS. **1** and **2** where the IFM has more than one ring;

FIG. **3** is a partially cross-sectioned exploded view of a proximal portion of a carrier tube and an alternative catheter, wherein the catheter includes a hub assembly having a hub and a snap-fit strain relief, with an IFM disposed on the strain relief;

FIG. **4** is an exploded isometric view of the catheter illustrated in FIG. **3**;

FIG. **5** is a partially cross-sectioned exploded view of a proximal portion of a carrier tube and an alternative catheter, wherein the catheter includes a hub assembly having a hub with a plurality of grip protrusions and a snap-fit strain relief, with an IFM disposed on the strain relief;

FIG. **6** is an exploded isometric view of the catheter illustrated in FIG. **5**;

FIG. **7** is a plan view of a proximal portion of an alternative catheter, wherein the catheter includes a hub assembly having a hub and an integral strain relief, with an IFM disposed on the hub;

FIG. **8** is a plan view of a proximal portion of an alternative catheter, wherein the catheter includes a hub assembly having a hub and a snap-fit strain relief, with an IFM disposed on the strain relief;

FIG. **9** is an exploded view of a proximal portion of a carrier tube and an alternative catheter, wherein the catheter includes a hub assembly having a hub and a snap-fit strain relief, with an IFM disposed on the strain relief, showing the IFM disengaged from the outside surface of the carrier tube;

FIG. **10** is a plan view of a proximal portion of a carrier tube and an alternative catheter, wherein the catheter includes a hub assembly having a hub and an integral strain relief, with an IFM disposed on the hub, showing the IFM disengaged from the outside surface of the carrier tube; and

FIGS. **11**–**15** are isometric views of a proximal portion of a carrier tube and alternative catheter designs, each with an IFM disposed on a double port hub assembly.

DETAILED DESCRIPTION OF THE INVENTION

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Refer now to FIG. **1** which illustrates a partially cross-sectioned plan view of a package **10** and an intravascular device **20** disposed therein. The package **10** includes a package wall **12** defining an elongate package lumen **14** therein. The package lumen **14** may be sized to accommodate substantially the entire length of the intravascular device **20** therein. The package lumen **14** may have an open proximal end and an open or closed distal end.

By way of example, not limitation, the package **10** is shown to be a carrier tube **10** having a carrier tube lumen **14** defined by a carrier tube wall **12**. Carrier tube **10** may be formed utilizing conventional materials, dimensions and techniques. For example, the carrier tube **10** may be formed of an extruded polymer comprising a blend of 50% polyolefin copolymer available under the trade name SURLYN and 50% high density polyethylene, having an inside diameter ranging from 0.10 to 0.30 inches, a wall thickness ranging from 0.002 to 0.020 inches, and a length ranging from 12 to 72 inches. Other suitable polymers for the carrier tube **10** include thermoplastics such as fluoropolymers (PTFE, FEP, PFA, CTFE), nylons, phenylene oxides, polyesters, polyethylenes, polypropylene, polyurethanes, combinations thereof, blends thereof, etc.

Intravascular device **20** is removably disposed in the lumen **14** of the carrier tube **10**. Intravascular device **20** generically refers to a wide variety of elongate intravascular devices such as catheters and guide wires. For example, the intravascular device may comprise a balloon catheter, a guide catheter, a diagnostic catheter, a guide wire, a drug delivery catheter, an atherectomy catheter, a tubular sheath, a stent delivery catheter, etc.

For purposes of illustration only, intravascular device **20** is shown in the form of an intravascular balloon catheter **20** having an elongate shaft **22**, a distally mounted balloon **24** and a stent **26** disposed thereon. A proximal portion **28** of the elongate shaft **2** is connected to a hub assembly **30**.

Hub assembly **30** includes a hub portion **32** and a strain relief **34**. The proximal portion **28** of the elongate shaft **22** extends through the strain relief **34** and into the hub **32**. The hub assembly **30** may be adhesively or thermally bonded to the proximal shaft portion **28**. Alternatively, the proximal portion **28** of the elongate shaft **22** may be connected to the hub assembly by an insert molding technique. As a further

alternative, the hub assembly **32** may be removably connected to the proximal shaft portion **28** utilizing a releasable compression fitting.

The hub **32** and the strain relief **34** may be a two-piece construction or a one-piece construction as shown. Examples of one-piece and two-piece constructions are described in U.S. Pat. No. 6,273,404 B1 to Holman et al, the entire disclosure of which is incorporated herein by reference. In one-piece constructions, the hub **32** and the strain relief **34** may be formed of the same material, such as polycarbonate. Other moldable polymeric material having sufficient impact resistance and chemical resistance may be utilized as well. In two-piece constructions, the hub **32** and the strain relief **34** may be formed of two different materials. For example, the hub may be formed of polycarbonate, and the strain relief may be formed of a relatively less rigid polymer such as polyurethane available under the trade name PELLETHANE.

The strain relief **34** reduces the tendency of the proximal shaft portion **28** to kink just distal of the hub **32**. Typically, the hub **32** is relatively stiff and rigid, whereas the shaft **22/28** is relatively flexible, which may create a stress concentration point therebetween, absent the strain relief **34**. Thus, the strain relief **34** provides a gradual transition in stiffness between the hub **32** and the proximal shaft portion **28**. In this particular embodiment, the strain relief **34** has a helical shape and a gradual reduction in profile, as described by Holman et al., to provide such a transition in stiffness.

In this particular embodiment, the hub **32** includes a single port fluid connector **36** for connection to an ancillary device such as an inflation device (not shown). The hub **32** may incorporate more than one connector **36**, or no connector at all, depending on the type of intravascular device **20** utilized. For example, an otherwise conventional guide wire may not require a fluid connector **36**, whereas an otherwise conventional over-the-wire (OTW) type balloon catheter may require a double port connector **36**.

Also in this particular embodiment, the hub assembly **30** includes a pair of wings **38** to facilitate easier handling and manipulation of the catheter **20**. The particular shape of the wings **38** may vary, depending on the manipulation requirements of the device **20**. In some instances, wings **38** may not be necessary or desirable.

The hub assembly **30** includes an interference fit member (IFM) **40** connected to a distal portion of the hub **32**, proximal of the strain relief **34**. The IFM **40** may be connected to any portion of the hub assembly **30**, or to any portion of the proximal shaft **28**. The IFM **40** may form an interference fit with any portion the carrier tube **10**, such as the inside surface of the carrier tube wall **12** as shown in FIG. **1**.

As seen in FIG. **1**, the carrier tube wall **12** and/or the IFM **40** has sufficient compressibility to deform and thereby permit the IFM **40** to enter into the carrier tube lumen **14** despite the nominal difference in size. The interference fit between the IFM **40** and the carrier tube **10** establishes sufficient friction to resist gravitational and handling forces which may otherwise cause the device **20** to fall out of the carrier tube **10**. The friction created by the interference fit may also be sufficiently small to permit easy removal of the device **20** from the carrier tube **10** as shown in FIG. **2**.

The IFM **40** may be sized and shaped to be fully or partially disposed inside the carrier tube lumen **14**. By fully extending the IFM **40** into the carrier tube lumen **14** a distance from the proximal end of the carrier tube **10**, the IFM **40** is less likely to be accidentally dislodged by rough handling or the like. To this end, the IFM **40** may establish a contact surface area with the inside surface of the carrier tube wall **14** that is distal of the proximal end of the carrier tube **10**.

In the embodiment illustrated in FIGS. **1** and **2**, the IFM **40** comprises a ring having middle portion **42** and end portions **44**. End portions **44** may be tapered and may have a diameter or profile that is less than the diameter or profile of the middle portion **42**. The middle portion **42** may have a diameter or profile that is greater than the inside diameter or inside profile of the carrier tube **10** adjacent the proximal end thereof. For example, the middle portion **42** may have a diameter or profile that is 0.0005 to 0.010 inches greater than the inside diameter or inside profile of the carrier tube **10**. Also by way of example, if the inside diameter of the carrier tube **10** is approximately 0.17 to 0.18 inches, the middle portion **42** may have a diameter of approximately 0.181 to 0.187 inches. In some embodiments, as shown in FIG. **2**A. the IFM **40** can comprise more than one ring.

The remaining FIGS. **3**–**15** described herein illustrate variations of the hub assembly **30** and IFM **40**. Except as described and evident from the drawings, the principles of design, function, use and manufacture may be the same as described previously. To this end, similar elements may be numbered the same or have the same last two digits.

Refer now to FIG. **3** which illustrates a partially cross-sectioned exploded view of the proximal portion of the carrier tube **10** and an alternative catheter **120**. The catheter **120** includes a hub assembly **130** having a hub **132** and a snap-fit strain relief **134**. The snap-fit strain relief **134** may be connected to the hub **132** utilizing a mechanical lock **150**. Mechanical lock **150** includes mating parts **152/154** which permit the strain relief **134** to be easily snap-fit onto the hub **132** to establish a rigid connection therebetween, as described by Holman et al.

An IFM **140** is disposed on the strain relief **134**. The IFM **140** may comprise a circular ring as shown in FIG. **2** or a plurality of protrusions distributed about the circumference of the strain relief **134** as illustrated in FIG. **4**. The IFM **140** includes a middle portion **142** and tapered end portions **144**. Middle portion **142** establishes an interference fit with the inside surface of the carrier tube wall **12**.

Refer now to FIG. **5** which illustrates a partially cross-sectioned exploded view of the proximal portion of the carrier tube **10** and an alternative catheter **220** disposed therein. The catheter **220** includes a hub assembly **230** having a hub **232** and a snap-fit strain relief **234**. The strain relief **234** may be connected to the hub **232** by a mechanical lock **250** as described by Holman et al. Hub **232** also includes a plurality of grip protrusions **233** disposed about the circumference of the hub **232** proximal of the strain relief **234** and distal of the wings **238** as best seen in FIG. **6**. Grip protrusions **233** enhance the ability of the physician to grip the hub assembly **230** to manipulate the catheter **220**.

An IFM **240** is disposed on the strain relief **234**. The IFM **240** may comprise a circular ring as illustrated in FIG. **2** or a plurality of protrusions distributed about the circumference of the strain relief **234** as shown in FIG. **6**. The IFM **240** includes a middle portion **242** and tapered end portions **244**. The middle portion **242** forms an interference fit with the inside surface of the carrier tube wall **12**.

Refer now to FIG. **7** which illustrates a plan view of a proximal portion of an alternative catheter **320**. Catheter **320** includes a hub assembly **330** having a hub **332** and an integral strain relief **334**. An IFM **340** is disposed on the hub **332** just proximal of the strain relief **334**. The IFM **340** comprises a thin ring having a middle portion **342** and a tapered proximal portion **344**. The middle portion **342**

engages the inside surface of the carrier tube wall **12** (not shown) to form an interference fit therebetween.

Refer now to FIG. **8** which illustrates a plan view of a proximal portion of an alternative catheter **420**. The catheter **420** includes a hub assembly **430** having a hub **432** and a snap-fit strain relief **434**. A mechanical lock **450** having mating members **452**/**454** mechanically connects the hub **432** to the strain relief **434** as described by Holman et al. An IFM **440** is disposed on a proximal portion of the strain relief **434**. The IFM **440** comprises a circular ring having a middle portion **442** and a proximal tapered portion **444**. The middle portion **442** of the IFM **440** engages the inside surface of the carrier tube wall **12** (not shown) to form an interference fit therebetween.

Refer now to FIG. **9** which illustrates an exploded view of the proximal portion of the carrier tube **10** and an alternative catheter **520** disposed therein. Catheter **520** includes a hub assembly **530** having a hub **532** and a snap-fit strain relief **534**. The hub **532** may be connected to the strain relief **534** by a mechanical connection **550** having mating elements **552**/**554** as described by Holman et al.

An IFM **540** is connected to the strain relief **534** distal of the mechanical connection **550**. The IFM **540** includes a pair of opposing flexure arms **542** each having one or more teeth **544**. Flexure arms **542** may bias the teeth **544** against the outside surface of the carrier tube wall **12**. The teeth **544** form an interference fit with the outside surface of the carrier tube wall **12**.

Refer now to FIG. **10** which illustrates a plan view of the proximal portion of the carrier tube **10** and an alternative catheter **620** disposed therein. The catheter **620** includes a hub assembly **630** having a hub **632** and an integral strain relief **634**. An IFM **640** is disposed on the hub **632** proximal of the strain relief **634**. The IFM **640** includes a pair of opposing flexure arms **642**, each having one or more teeth **644**. Flexure arms **642** bias the teeth **644** against the outside surface of the carrier tube wall **12** to establish an interference fit therebetween.

Refer now to FIGS. **11**–**15** which illustrate isometric views of the proximal portion of the carrier tube **10** and alternative designs of a catheter **720** having a double port hub assembly **730**. The double port hub assembly **730** is particularly suitable for over the wire (OTW) type balloon catheters. The hub assembly **730** includes a pair of port connectors **736**.

In each of the embodiments illustrated in FIGS. **11**–**15**, the hub assembly **730** includes a hub portion **732** and a strain relief portion **734**. Also in each of the embodiments illustrated in FIGS. **11**–**15**, an IFM **740** in the form of a plurality of protrusions is disposed on a portion of the hub assembly **730**. Each of the protrusions **740** includes a middle portion **742** and tapered end portions **744**. The middle portion **742** forms an interference fit with the inside surface of the carrier tube wall **12**.

In the embodiments illustrated in FIGS. **11** and **12**, the hub **732** and the strain relief **734** are integrally formed as described by Holman et al. In the embodiments illustrated in FIGS. **13**–**15**, the hub **732** and the strain relief **734** comprise a two-piece construction that may be snap-fit together using a mechanical connection **750** including mating members **752** and **754** as described by Holman et al.

In the embodiments described in FIGS. **11**, **12** and **15**, the IFM **740** is disposed on a distal portion of the hub **732**. In the embodiments illustrated in FIGS. **13** and **14**, the IFM **740** is disposed on the strain relief **734**.

In the embodiments illustrated in FIGS. **11** and **13**, the IFM **740** comprises four protrusions distributed about the circumference of hub assembly **730** spaced apart by approximately 90 degrees. In the embodiments illustrated in FIGS. **12**, **14** and **15**, the IFM **740** comprises six protrusions spaced approximately 60 degrees apart about the circumference of the hub assembly **730**.

Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

What is claimed is:

1. An intravascular device suitable for packaging in a package lumen defined by a package lumen wall, the intravascular device comprising:

an elongate shaft having a proximal portion; and

a hub assembly connected to the proximal portion of the elongate shaft, the hub assembly including an interference fit member (IFM) which is configured to form an interference fit with the package lumen wall when the intravascular device is disposed in the package lumen;

wherein the interference fit establishes sufficient friction to resist gravitational and handling forces which may otherwise cause the intravascular device to fall out of the package lumen;

wherein the friction created by the interference fit is sufficiently small to permit easy removal of the intravascular device from the package lumen; and

wherein the IFM comprises one or more rings.

2. An intravascular device as in claim **1**, wherein the one or more rings has a middle portion and a distal end portion and a proximal end portion.

3. An intravascular device as in claim **2**, wherein the middle portion of the ring has a larger diameter than the end portions.

4. An intravascular device as in claim **2**, wherein the end portions taper from the diameter of the middle portion to a smaller diameter than the middle portion.

5. An intravascular device as in claim **1**, wherein the one or more rings has a middle portion and a proximal tapered portion.

6. An intravascular device suitable for packaging in a package lumen defined by a package lumen wall, the intravascular device comprising:

an elongate shaft having a proximal portion; and a hub assembly connected to the proximal portion of the elongate shaft, the hub assembly including an interference fit member (IFM) which is configured to form an interference fit with the package lumen wall when the intravascular device is disposed in the package lumen;

wherein an inner diameter of the package lumen wall is smaller than the outer diameter of the IFM such that the IFM deforms the package lumen wall when the IFM is in an interference fit with the package lumen wall; and

wherein the IFM causes the package lumen wall to bulge outwardly when the IFM is disposed within the package lumen wall.

7. An intravascular device suitable for packaging in a package lumen defined by a package lumen wall, the intravascular device comprising:

an elongate shaft having a proximal portion; and

a hub assembly connected to the proximal portion of the elongate shaft, the hub assembly including an interference fit member (IFM) which is configured to form an interference fit with the package lumen wall when the intravascular device is disposed in the package lumen;

wherein the interference fit establishes sufficient friction to resist gravitational and handling forces which may otherwise cause the intravascular device to fall out of the package lumen;

wherein the friction created by the interference fit is sufficiently small to permit easy removal of the intravascular device from the package lumen;

wherein the hub assembly includes a hub and a strain relief, and wherein the IFM is carried by the hub; and

wherein the IFM is disposed on a distal end of the hub, proximal the strain relief.

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